



November 14, 2024

Via CM/ECF

The Honorable Jennifer L. Hall
J. Caleb Boggs Federal Building
Unit 17, Room 6312
844 North King Street
Wilmington, DE 19801-3555

Re: *Ingenus Pharmaceuticals, LLC v. Hetero USA, Inc. et al.*
C.A. No. 24-1025-JLH

Dear Judge Hall:

Pursuant to Your Honor's October 7, 2024 Oral Order, I write jointly on behalf of Plaintiff Ingenus Pharmaceuticals, LLC ("Ingenus") and Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI ("Hetero") (collectively, "the Parties") to submit the attached proposed Scheduling Order. Below, the parties address the information requested in the Oral Order:

(a) Description of what this case is about.

This case is Hatch-Waxman patent infringement litigation concerning Cyclophosphamide Solution, which is an injectable solution indicated for the treatment of malignant diseases such as malignant lymphomas (Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma); multiple myeloma, leukemias (chronic lymphocytic leukemia, chronic granulocytic leukemia, acute myelogenous and monocytic leukemia, acute lymphoblastic (stem-cell) leukemia); mycosis fungoides, neuroblastoma, adenocarcinoma of the ovary, retinoblastoma, and breast carcinoma. Ingenus is the owner and licensor of NDA No. 212501. The active ingredient in Plaintiff's NDA product is cyclophosphamide.

Ingenus is the sole owner and assignee of U.S. Patent No. 10,993,952 ("the '952 Patent"). The '952 Patent is listed in the FDA Orange Book for Cyclophosphamide Injection.

Hetero is the owner of ANDA No. 219271 for FDA approval to manufacture, use and sell cyclophosphamide injection. In July 2024, Hetero notified Ingenus that it had filed a Paragraph IV certification with the FDA, asserting that the '952 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Hetero's Proposed ANDA Product.

Ingenus filed this lawsuit on September 11, 2024.

Page 2

(b) The parties' positions regarding any disputes in the proposed Scheduling Order.

The parties do not have any disputes in the proposed Scheduling Order.

(c) List of any other issues the parties want to address at the Rule 16 Scheduling Conference.

The parties do not have any other issues to address at the Rule 16 Scheduling Conference.

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Counsel is available at the Court's convenience should Your Honor have any questions.

Respectfully submitted,

/s/ Daniel A. Taylor

Daniel A. Taylor (No. 6934)

cc: Counsel of record (via CM/ECF and email)